

## REMARKS

### **Status of the Claims**

Claims 1, 4, 5, 9, 10, 12, 14, 15, 17, 8, 22, 23, 25, 27-45, 47 and 48 were pending.

Claims 15, 17, 8, 22, 23, 25, 27-42, 47 and 48 were withdrawn from consideration. By amendment herein, claim 1 now explicitly recites that the composition includes arginine phosphate and CHAPs. Accordingly, claims 4 and 9 as well as withdrawn claims 17 and 22 have been canceled without prejudice or disclaimer. Claims 5, 10, 18 and 23 have been amended for proper antecedent basis. Thus, claims 1, 5, 10, 12, 14, 15, 8, 23, 25, 27-45, 47 and 48 are pending as shown above and claims 1, 5, 10, 12, 14, 43 and 44 are under active examination.

Furthermore, as the withdrawn method claims contain all the limitations of the examined composition claims, rejoinder of the method claims upon indication of allowable subject matter is in order.

### **Rejection Withdrawn**

Applicants note that the amendments after final obviated the previous rejections under 35 U.S.C. § 102. (Advisory Action, page 2).

### **35 U.S.C. § 112, 1<sup>st</sup> paragraph**

Previous claims 1-12, 14 and 43-45 were rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph as not enabled throughout their scope by the as-filed specification. (Advisory Action, page 2). It was alleged that only compositions comprising an LTK63 protein and arginine phosphate and CHAPs are enabled. *Id.*

The foregoing amendments obviate the rejections with regard to the stabilizing agents by specifying arginine phosphate and CHAPs.

In regards to the protein component, Applicants again note that the specification fully enables stabilizing of any AB5 LT or CT protein with arginine phosphate and the zwitterionic detergent CHAPs, as claimed. Enablement is not judged by what is exemplified in the specification (in this case stabilization of LTK63), but by what the specification (and art at the time of filing) discloses would be routine to the skilled artisan. As previously noted, it would be completely routine based on the teachings of the specification and the art as a whole for the

skilled artisan to provide compositions comprising other LT or CT toxin in combination with arginine phosphate and CHAPs. In fact, LT and CT holotoxins (mutants or otherwise) were, at the time of filing, known to be very similar in structure and function. *See, e.g.*, pages 13-14, noting the well-characterized nature of CT and LT endotoxins and that these two proteins are “structurally, functionally and immunologically” similar, including in that LT and CT are immunologically cross-reactive. Thus, the skilled artisan would know that any LT or CT protein could be used in the claimed compositions. Accordingly, withdrawal of the rejection is in order.

**CONCLUSION**

In view of the foregoing, Applicants submit that the claims are in condition for allowance.

Please direct all further communications regarding this application to:

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Respectfully submitted,

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